

REMARKS

In the Office Action mailed August 24, 2004, the Examiner rejected claim 1 of the present application on various grounds. One rejection that was given was the rejection on the obviousness-double patenting grounds over claims 1-4 of U.S. Patent No. 6,638,767, claims 1-35 of U.S. Patent 6,743,779, claim 125 of U.S. Patent No. 5,830,430, claims 73-81 of U.S. Patent No. 6,056,938, and claim 12 of U.S. Patent No. 5,997,898 (page 2 of the Office Action mailed August 24, 2004, page 2, last paragraph).

The counsel of record at that time responded to all the rejections on February 9, 2005, except the obviousness-double patenting rejection, with respect to which the counsel asked to hold the rejection in abeyance. The counsel stated that the filing of a terminal disclaimer will be considered upon notification of allowable subject matter (see, Amendment filed February 9, 2005, page 22, lines 1-2). In the Office Communication mailed January 9, 2006, the Examiner stated that it would be improper to hold this rejection in abeyance and required to respond to the obviousness-double patenting rejection on the merits.

On February 3, 2006, the Examiner and the undersigned have conducted a telephone discussion to clarify the issues related to the obviousness-double patenting rejection. It was pointed out to the Examiner that the obviousness-double patenting rejection of claim 1 no longer applies because claim 1 was canceled by the Amendment filed February 9, 2005. The Examiner has pointed out that new claims 105-120 were added by the same Amendment. The undersigned has stated that there has never existed an obviousness-double patenting rejection with regard to claims 105-120. The Examiner has agreed, but stated that the obviousness-double patenting rejection of claim 1 should nevertheless be construed as applicable also to claims 105-120 and has required to respond on the merits.

In view of the foregoing, the Applicants hereby comply with the Examiner's requirement to respond to the obviousness-double patenting rejection, and traverse the rejection on the following grounds.

With regard to the rejections over U.S. Patent No. 6,638,767 ("the '767 patent") and U.S. Patent No. 6,743,779 ("the '779 patent"), it is submitted that the rejection is moot in view of the terminal disclaimer that accompanies this response.

With regard to the rejection over U.S. Patent No. 5,830,430 ("the '430 patent"), it is submitted that claims 105-120 are patentably distinguishable over claim 125 of the '430 patent. Indeed, claims 105-118 claim using a mixture which does not include a liposome. At the same time, by the virtue of its dependency on claim 118, claim 125 of the '430 patent recites a method "for delivering intracellularly a bioactive agent comprising contacting a cell with a cationic lipid composition which comprises the cationic lipid compound."

Thus, the method of claim 125 requires using "a cationic lipid composition." Accordingly, the inventions recited in claims 105-118 of the present application and claim 125 of the '430 patent are directed to mutually exclusive embodiments, i.e., one specifically excluding lipids and the other explicitly requiring the presence of lipids.

As to claims 119-120 of the present application, the ultrasound at the energy level of 200-500 mW per cm² is recited. Claim 125 of the '430 patent is completely silent with respect to the energy levels to be used. The specification of the '430 patent does describe using the energies between 50 mW and 5 W, but does not describe the level of the energy flux (i.e., wattage per 1 cm² of the surface) that is to be used. It is submitted that the '430 patent provides no suggestion or motivation to one skilled in the art to use the energy level of 200-500 mW per cm². Accordingly, the subject matter recited in claims 119-120 is non-obvious over claim 125 of the '430 patent.

Thus, the claims of the present application claim the matter that is non-obvious over what is disclosed in the '430 patent. It is, therefore, submitted that the obviousness-double patenting rejection over claim 125 of the '430 patent does not apply.

With regard to the rejection over U.S. Patent No. 6,056,938 ("the '938 patent"), it is submitted that claims 105-118 claim using a mixture which does not include a

liposome, as discussed above. At the same time claims 73-81 of the '938 patent recite a cationic lipid composition.

Accordingly, one skilled in the art would not have been motivated to modify the invention recited in the inventions recited in claims 73-81 of the '938 patent to arrive at the invention of claims 105-118 of the present application, because the inventions of the present application are directed to embodiments that exclude embodiments of the '938 patent, i.e., one specifically excluding lipids and the other explicitly requiring the presence of lipids.

As to claims 119-120 of the present application, the ultrasound at the energy level of 200-500 mW per cm² is recited. Claims 73-81 of the '938 patent are silent with respect to the energy levels to be used. The specification of the '938 patent does describe using the energies between 50 mW and 5 W, but does not describe the level of the energy flux that is to be used, as discussed above for the '430 patent. Accordingly, the subject matter recited in claims 119-120 is non-obvious over what is disclosed in the '938 patent.

Thus, the claims of the present application claim the matter that is non-obvious over the '938 patent. It is, therefore, submitted that the obviousness-double patenting rejection over claims 73-81 of the '938 patent does not apply.

With regard to the rejection over U.S. Patent No. 5,997,898 ("the '898 patent"), it is submitted that claims 105-120 of the present application require using organic halide, while claim 12 of the '898 neither discloses nor suggests using any organic halides. All that claim 12 is directed to is sulfur hexafluoride, which is not an organic substance. It is, therefore, submitted that the obviousness-double patenting rejection over claim 12 of the '898 patent does not apply.

In view of the foregoing, reconsideration and withdrawal of the obviousness-double patenting rejection is respectfully requested. Should any questions remain in view of this communication, the Examiner is encouraged to call the undersigned so that a prompt disposition of this application can be achieved.

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Enclosed is Check No. 580810 in the amount of \$65.00 to cover the terminal disclaimer fee. No other fees are deemed necessary. However, the Commissioner is hereby authorized to charge any additional fees associated with the filing submitted herewith, or credit any overpayment, to Deposit Account No. 07-1896.

Respectfully submitted,

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